

Filed: March 31, 2023

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

WUHAN HEALTHGEN BIOTECHNOLOGY CORP.,
Petitioners,

v.

VENTRIA BIOSCIENCE INC.,
Patent Owner.

Case No. IPR2023-00684
Patent No. 11,492,389

PETITIONER'S EXHIBIT LIST

Pursuant to 37 C.F.R. § 42.63(e), Petitioner Wuhan Healthgen Biotechnology Corp., hereby submits a current listing of Petitioner's exhibits.

Exhibit	Description
1001	U.S. Patent No. 11,492,389, issued Nov. 8, 2022
1002	Prosecution History of U.S. Patent No. 11,492,389 (excerpted to exclude prior art publications included therein)
1003	Declaration of Douglas S. Clark, Ph.D.
1004	U.S. Patent Publication No. 2007/0166825 ("Hatsuyama")
1005	WO 2007/002762 ("Deeter")
1006	Prosecution History of U.S. Patent No. 10,618,951 (excerpts)
1007	U.S. Patent Publication No. 2006/0110399 ("Van Holten")
1008	U.S. Patent Publication No. 2006/0194300 ("Schulz")
1009	U.S. Patent Publication No. 2006/0008792 ("Viswanathan")
1010	Jayme et al., "Basal Medium Development for Serum-Free Culture: a Historical Perspective," <i>Cytotechnology</i> , 23:95-101 (1997) ("Jaymne")
1011	Castilho et al., "Animal Cell Technology: From Biopharmaceuticals to Gene Therapy," (Castilho, Moraes, Augusto, and Butler, Eds.) (New York, Taylor & Francis Group, 2008) ("Castilho")
1012	Glassy et al., "Serum-Free Media in Hybridoma Culture and Monoclonal Antibody Production," <i>Biotechnology and Bioengineering</i> , vol. 32, 1015-1028 (1988) ("Glassy")
1013	Peters, T., "All About Albumin [subtitled:] Biochemistry, Genetics, and Medical Applications," (Peters, T., Ed.) (New York, Academic Press, 1996) ("Peters")

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1014	Dockal et al., "The Three Recombinant Domains of Human Serum Albumin," <i>The Journal of Biological Chemistry</i> , vol. 274, no. 41, 29303-29310 (1999) ("Dockal")
1015	Simard et al., "Locating High-Affinity Fatty Acid-Binding Sites on Albumin by X-Ray Crystallography and NMR Spectroscopy," <i>Proceedings of the Nat'l Acad. of Sci.</i> , vol. 102, no. 50, 17958=17963 (2005) ("Simard")
1016	J.K. Fuller Noel and M. J. Hunter, "Bovine Mercaptalbumin and Non-mercaptalbumin Monomers," <i>J. Biological Chemistry</i> , vol. 247, no. 22, 7391-7406 (1972) ("Noel and Hunter")
1017	Atmeh et al., "Albumin Aggregates: Hydrodynamic Shape and Physico-Chemical Properties," <i>Jordan J. of Chemistry</i> , vol. 2, no. 2, 169-182 (2007) ("Atmeh")
1018	K. Griebenow and A.M. Klibanov, "Lyophilization-Induced Reversible Changes in the Secondary Structure of Proteins," <i>Proc. Nat'l Acad. Sci. USA</i> , vol. 92, 10969-10976 (Nov. 1995) ("Griebenow and Klibanov")
1019	P. Matejtschuk, et al., "Production of Human Albumin Solution: a Continually Developing Colloid," <i>Br. J. Anaesth.</i> , vol. 85, 887-95 (2000) ("Matejtschuk")
1020	J. Brandt and L-O Anderson, "Heat Denaturation of Human Serum Albumin. Migration of Bound Fatty Acids," <i>Int. J. Peptide Protein Res.</i> , vol. 8, 33-37 (1976) ("Brandt and Anderson")
1021	F. Garcia-Gonzalo et a., "Albumin-Associated Lipids Regulate Human Embryonic Stem Cell Self-Renewal," <i>PLoS One</i> , (2008), Issue 1, e1384 ("Garcia-Gonzalo")
1022	Jurgens et al., "Investigation into the Interaction of Recombinant Human Serum Albumin with Re-lipopolysaccharide and Lipid A," <i>J. of Endotoxin Research</i> , vol. 8, no. 2, 115-126 (2002) ("Jurgens")
1023	David et al., "Characterization of the Interaction of Lipid A and Lipopolysaccharide with Human Serum Albumin: Implications for an Endotoxin Carrier Function for Albumin," <i>J. of Endotoxin Research</i> , vol. 2, 99-106 (1995) ("David")
1024	U.S. Patent No. 7,304,208 titled "Expression of Human Serum Albumin (HSA) in Monocot Seeds"

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1025	Schenerman et al., "Characterization of Alternatives to Animal-Derived Raw Materials [subtitle:] 'Animal-Free' May Not Mean 'Problem Free,'" <i>BioProcess Technical</i> , 42-47 (Sept. 2003) ("Schenerman")
1026	M. Gorbet & M. Sefton, "Endotoxin: The Uninvited Guest," <i>Biomaterials</i> , vol. 26, 6811-6817 (2005) ("Gorbet")
1027	J. Ryan, "Endotoxins in Cell Culture," <i>Corning Life Sciences Technical Bulletin</i> , 1-8 (2004) ("Ryan")
1028	G. Hewlett, "Strategies for Optimising Serum-Free Media," <i>Cytotechnology</i> , vol. 5, 3-14 (1991) ("Hewlett")
1029	M. Dawson, "The Significance of Endotoxin to Cell Culture and Biotechnology," <i>LAL Update</i> , March 1998, vol. 16, no. 1 ("Dawson")
1030	J. Majde, "Microbial Cell-Wall Contaminants in Peptides: A Potential Source of Physiological Artifacts," <i>Peptides</i> , vol. 14, 629-632 (1993) ("Majde")
1031	"Molecular Farming," (R. Fischer and S. Schillberg, Eds., Wiley-VCH, Germany) (2004) ("Molecular Farming")
1032	Van der Valk et al., "The Humane Collection of Fetal Bovine Serum and Possibilities for Serum-Free Cell and Tissue Culture," <i>Toxicology in Vitro</i> , vo. 18, 1-12 (2004) ("Van der Valk")
1033	Kusnadi et al., "Production of Recombinant Proteins in Transgenic Plants: Practical Considerations," <i>Biotechnology and Bioengineering</i> , vol. 56, no. 5, 473-484 (Dec. 5, 1997) ("Kusnadi")
1034	Sijmons et al., "Production of Correctly Processed Human Serum Albumin in Transgenic Plants," <i>Biotechnology</i> , vol. 8, 217-221 (March 1990) ("Sijmons")
1035	Farran et al., "Targeted Expression of Human Serum Albumin in Potato Tubers," <i>Transgenic Res.</i> , vol. 11, 337-346 (2002) ("Farran")
1036	Huang et al., "Production of Human Serum Albumin by Sugar Starvation Induced Promoter and Rice Cell Culture," <i>Transgenic Res.</i> , vol. 14, 569-581 (2005) ("Huang")
1037	L. Bito, "Inflammatory Effects of Endotoxin-Like Contaminants in Commonly Used Protein Preparations," <i>Science</i> , vol. 196, 83-85 (1977) ("Bito")

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1038	T-K Huang and K. McDonald, "Bioreactor Engineering for Recombinant Protein Production in Plant Cell Suspension Cultures," <i>Biochemical Eng'r Journal</i> , vol. 45, 168-184 (2009) ("McDonald")
1039	Larrick et al., "Production of Secretory IgA Antibodies in Plants," <i>Biomolecular Eng'r</i> , vol. 18, 87-94 (2001) ("Larrick")
1040	Brereton et al., "Single Chain Antibody Fragments for Ocular Use Produced at High Levels in a Commercial Wheat Variety," <i>J. of Biotechnology</i> , vol. 129, 539-546 (2009) ("Brereton")
1041	Fujiwara et al., "Extraction and Purification of Human Interleukin-10 from Transgenic Rice Seeds," <i>Protein Expression and Purification</i> , vol. 72, 125-130 (2010) ("Fujiwara")
1042	Magalhaes et al., "Methods of Endotoxin Removal from Biological Preparations: a Review," <i>J. Pharm. Pharmaceut. Sci.</i> , 10(3): 388-404 (2007) ("Magalhaes")
1043	D. Petsch and F. Birger Anspach, "Endotoxin Removal from Protein Solutions," <i>J. of Biotechnology</i> , 76 (2000) 97-119 ("Petsch")
1044	Y. Aida and M. Pabst, Removal of Endotoxin from Protein Solutions by Phase Separation using Triton X-114," <i>J. Immunological Methods</i> , 132 (1990) (191-195) ("Aida")
1045	Elsheikh et al., "Manipulated Mouse Embryos as Bioassay for Water Quality Control," <i>Reproduction in Domestic Animals</i> , 38(3), 204-208 (2003) ("Elsheikh")
1046	Reichelt et al., "Single Step Protocol to Purify Recombinant Proteins with Low Endotoxin Contents," <i>Protein Expression and Purification</i> , 46 (2006) 483-388 ("Reichelt")
1047	Jahan et al., "Toxicity of Nonionic Surfactants," <i>Environ. Toxicology II</i> , 281-290 (2008) ("Jahan")

Exhibit	Description
1048	Weyermann et al., "A Practical Note on the Use of Cytotoxicity Assays," <i>Int'l J. of Pharmaceutics</i> , 288 (2005) 369-376 ("Weyermann")
1049	Burnouf et al., "Comparative Removal of Solvent and Detergent Viral Inactivating Agents from Human Intravenous Immunoglobulin G Preparations using SDR Hyper D and C18 Sorbents," <i>Analytical Biochemistry</i> , 389 (2009) 69-73 ("Burnouf")
1050	Piquet et al., "Virus Inactivation of Fresh Frozen Plasma by a Solvent Detergent Procedure: Biological Results," <i>Vox Sang</i> , 1992, 63:251-256 ("Piquet")
1051	Guerrier et al., "Specific Sorbent to Remove Solvent-Detergent Mixtures from Virus-Inactivated Biological Fluids," <i>Journal of Chromatography B</i> , 664 (1995) 119-125 ("Guerrier")
1052	Wang et al., "Cloud Point of Nonionic Surfactant Triton X-45 in Aqueous Solution," <i>Colloids and Surfaces B: Biointerfaces</i> , 61 (2008) 118-122 ("Wang")
1053	Tanaka et al., "Isolation of Bovine Plasma Albumin by Liquid Chromatography and its Polymerization for Use in Immunohematology," <i>Brazilian J. of Medical and Biological Res.</i> , 34:977-983 (2001) ("Tanaka")
1054	Jachimska et al., "Characterization of Globular Protein Solutions by Dynamic Light Scattering, Electrophoretic Mobility, and Viscosity Measurements," <i>Langmuir</i> , 24:6866-6872 (2008) ("Jachimska")
1055	Brahma et al., "Characterization of a Dimeric Unfolding Intermediate of Bovine Serum Albumin under Mildly Acidic Conditions," <i>Biochimica et Biophysica Acta</i> , 1751 (2005) 159-169 ("Brahma")
1056	Gorin et al., "The Evolution of α -Feroprotein and Albumin," <i>J. Biological Chemistry</i> , vol. 256, no. 4, 1954-1959 (Feb. 25, 1981) ("Gorin")

Exhibit	Description
1057	U.S. Department of Health and Human Services, Food and Drug Administration, Center for Biologics Evaluation and Research, "Guidance for FDA Reviewers and Sponsors," April 2008 ("2008 FDA Guidance")
1058	<i>Certain Plant-Derived Recombinant Human Serum Albumins ("rHSA") and Products Containing Same</i> , Inv. No. 337-TA-1238, Transcript of Open Sessions (U.S.I.T.C. Nov. 21, 2021)
1059	U.S. Patent No. 5,094,960 ("Bonomo")
1060	U.S. Provisional Application No. 61/154,204

Respectfully Submitted

Date: March 31, 2023

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), the undersigned certifies that on March 31, 2023, copies of the foregoing **PETITIONER'S EXHIBIT LIST** and **Wuhan Healthgen Exhibits 1001 through 1060** were served by FedEx on the correspondence address of record indicated in the Patent Office's public PAIR system for U.S. Patent No. 11,492,389:

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